

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Self-Assessment of a Pharmacy by the Pharmacist-in-Charge

Section Affected: 1715

Problem Addressed

The Pharmacy Act (Business and Professions Code sections 4000 et seq.) authorizes the Board of Pharmacy to establish and implement rules and regulations regarding the practice of pharmacy as may be necessary for the protection of the public.

In order to conduct a pharmacy in California, the pharmacy permit holder must place a registered pharmacist in charge of the pharmacy. This individual is responsible for the operations of the pharmacy and is designated the pharmacist-in-charge (PIC).

Currently, PICs are using an outdated version of the forms that detail the periodic self-assessment of pharmacy operations. These forms are designed to provide comprehensive information regarding compliance requirements for federal and state laws to each pharmacy in a readily understandable format. The PIC is held responsible for a pharmacy's compliance with these requirements even though currently the self-assessment form is out of date.

In addition, the current forms lack a reference to the board's web site which contains a wealth of information regarding the board and the practice of pharmacy. While pharmacists are advised through the board's newsletter of this web address, the board wishes to provide it at every reasonable opportunity.

The proposed regulatory amendment is based upon the board's desire to provide timely and relevant information to its licensees and permit holders in a format that is conducive to understanding the board's expectations with regard to compliance with pharmacy law. The ultimate beneficiaries are California pharmacy patients who will be served by pharmacy staff that have an increased awareness of the importance of compliance with current laws that are relevant to pharmacy practice.

Finally, the board seeks to amend the statutory references listed with the exact language due to changes in the format of its laws. This amendment is without regulatory impact.

Specific Purpose of the Regulation

The purpose of this proposal is to: 1) amend the existing self-assessment forms (for both community and hospital practice settings) to reflect current and complete references to Pharmacy Law, 2) clarify existing entries that have confused the pharmacists-in-charge (PICs) who must complete the forms, and 3) amend the exact language of section 1715 to move the mandated

compliance date from March 31 of each odd-numbered year to July 1 of each odd-numbered year -- a recognizable milestone date that is consistent with beginning of the state's fiscal year. This date is frequently used by the board for data tracking purposes to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance.

Due to the nature of the forms, , it is not possible to present the proposed changes in the customary strikeout and underline format. Therefore, the board has provided copies of each form in the current version as well as the proposed amended version. In order to facilitate comparison of the two versions, the board has included a narrative that outlines each change and its appearance on the proposed amended version.

Factual Basis

Pursuant to Business and Professions Code section 4005 the Board of Pharmacy has the authority to promulgate regulations to regulate the practice of pharmacy.

The board is charged with the responsibility of protecting the public health, safety and welfare. Board of Pharmacy inspectors and staff accomplish this task in part by conducting inspections of pharmacies and responding to inquiries from licensees regarding pharmacy law. When a pharmacy is inspected, the PIC is in charge of assuring a pharmacy's compliance with state and federal requirements. He or she is able to do so in part because the board has implemented the use of self-assessment forms.

When PICs complete the self-assessment form, they increase their pharmacy's compliance with legal requirements without waiting for a board inspection. Additionally PICs are provided with information on the forms that can answer many of their questions, In the past PICs directed these questions to board inspectors and staff. There is a significant benefit to the public when a pharmacy is in compliance with the law.

Section 4029 defines "hospital pharmacy."

Section 4030 defines "intern pharmacist."

Section 4037 defines "pharmacy."

Section 4040 defines "prescription" and who may prescribe.

Sections 4051 and 4052 establish the parameters of the practice of pharmacy.

Section 4105 establishes the criteria for making and retaining pharmacy records.

Section 4113 establishes the requirement that each pharmacy be in the charge of a registered pharmacist who has been designated a "pharmacist-in-charge" (PIC).

Section 4115 sets forth the duties of a pharmacy technician.

Section 4119 establishes the criteria for furnishing drugs to a specified licensed facility.

Section 4305 establishes the requirements regarding the reporting to the board the termination of services for a pharmacist who was the PIC of a pharmacy.

The board desires to provide all parties who must use the self-assessment forms, with a document that is straightforward and accurately represents the information they need to comply with California and federal requirements for the practice of pharmacy.

Underlying Data

None

Business Impact

This regulation would not have significant adverse economic impact on businesses.

This action would provide a PIC with the updated specific compliance information that the board seeks when conducting a pharmacy audit. The requirements for conducting a pharmacy outlined in the self-assessment are not new requirements and pharmacies are already required to comply with them.

The board intends that a PIC would have the most current and user-friendly version of the mandated forms that allow a PIC to determine the extent to which the pharmacy is or is not in compliance with pharmacy law, make adjustments to bring the pharmacy into compliance and thereby improve the pharmacy's performance in meeting state and federal requirements.

This would benefit public safety. Moreover, an updated assessment form would provide pharmacies and the PIC with the knowledge they need to comply with California and federal requirements for the practice of pharmacy.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No alternative which was considered would be either more effective than or equally as effective and less burdensome to affected private persons than the proposed regulation.

(11/21/00)